Filed October 26, 2001

Request for Continued Examination dated July 24, 2006

Atty. Docket: PEDI-04 (formerly KIEL-02)

Listing of Claims

1. (Presently Amended) A composition comprising:

a plurality of active pharmaceutical ingredients consisting essentially of

phenylephrine and pyrilamine, the composition formed from a method comprising:

forming a solution by dissolving the salt or free base of said active

pharmaceutical ingredients in a solvent;

forming a dispersion by mixing a dispersing agent and tannic acid in a

solvent;

combining the solution and the dispersion, to form tannate salts of the

active pharmaceutical ingredients; and

combining the tannate salts without isolation or purification with at least

one suspending agent to produce a homogeneous suspension including

pharmaceutically active tannate salts, the homogeneous suspension being in an

amount including a plurality of dosage units, the homogeneous suspension being

homogeneous in amounts of active pharmaceutical ingredients in each of the dosage

units when compared with each of the other dosage units.

2. (Original) The composition of claim 1 wherein the active pharmaceutical ingredients

are present in a range of about 0.05% to about 25.0% by weight.

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3. (Previously Amended) The composition of claim 1 wherein the active pharmaceutical

ingredients are selected from the group of salts consisting of maleate, citrate, chloride,

bromide, acetate, and sulfate, and combinations thereof.

4. (Original) The composition of claim 1 wherein the tannic acid is natural or synthetic.

5. (Previously Amended) The composition of claim 1 wherein the dispersing agent is

selected from the group consisting of magnesium aluminum silicate, xanthan gum and

cellulose compounds, and combinations thereof.

6. (Original) The composition of claim 5 wherein the dispersing agent is magnesium

aluminum silicate and is present in a range of about 0.05% to about 5.0% by weight.

7. (Original) The composition of claim 1 wherein the tannic acid is present in a range of

about 0.05 to about 10.0% by weight.

8. (Original) The composition of claim 6 wherein the magnesium aluminum silicate and

tannic acid are present by weight in a ratio in the range of 0.1:1 to 100:1.

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9. (Original) The composition of claim 1 wherein the tannic acid and the active

pharmaceutical ingredients are present by weight in a ratio in the range of 2:1 to 10:1.

10. (Original) The composition of claim 1 wherein the thickening agent is magnesium

aluminum silicate and is present in a range of about 0.5% to about 10.0% by weight.

11. (Original) The composition of claim 1 wherein the suspending agent is kaolin and is

present in a range of about 0.5 to about 10.0% by weight.

12. (Original) The composition of claim 1 wherein the sweetening agents include

sucrose present in a range of about 5.0% to about 50.0% by weight, and saccharin

sodium present in a range of about 0.01% to about 3.0% by weight.

13. (Original) The composition of claim 1 wherein the flavoring agent is artificial grape

and is present in a range of about 0.01% to about 2.0% by weight.

14. (Original) The composition of claim 1 wherein the second solvent is water and is

present in a range of about 10.0 to about 75.0% by weight.

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15. (Original) The composition of claim 1 wherein said second solvent is glycerin and is

present in a range of about 2.5% to about 20.0% by weight.

16. (Original) The composition of claim 1 wherein the preservative is methylparaben and

is present in a range of about 0.01 to about 1.0% by weight.

17. (Original) The composition of claim 1 wherein the pH adjusting agent is benzoic acid

and is present in a range of about 0.05 to about 1.0% by weight.

18. (Original) The composition of claim 1 wherein the anti-caking agent is pectin and is

present in the range of about 0.5 to about 10.0% by weight.

19. (Original) The composition of claim 1 wherein the pH of said liquid dosage form is in

a range of about 3.5 to 6.5.

20. (Original) The composition of claim 1 wherein the pharmaceutically active tannate

salts are pyrilamine tannate present at about 30mg and phenylephrine tannate present

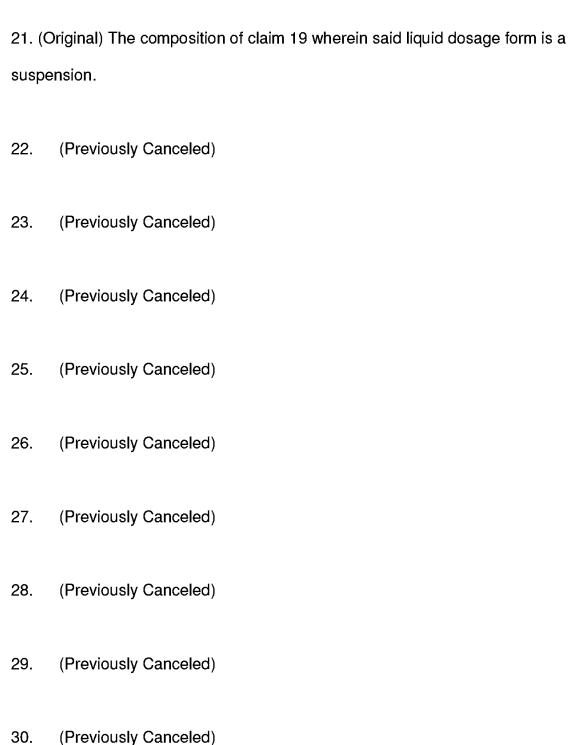
at about 12.5mg.

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31. (Presently Amended) A composition comprising:

a plurality of active pharmaceutical ingredients consisting essentially of

phenylephrine and pyrilamine, the composition formed from a method comprising:

forming a solution by dissolving the salt or free base of said active

pharmaceutical ingredients in a solvent;

forming a powder mixture by mixing a dispersing agent, diluent and tannic

acid;

combining the solution and the powder mixture to form tannate salts of the

active pharmaceutical ingredients; and

combining the tannate salts without isolation or purification with at least

one tablet excipient to prepare a homogeneous granulation including pharmaceutically

active tannate salts, the homogeneous granulation being in an amount to include a

plurality of dosage units, the homogeneous granulation being homogeneous in amounts

of active pharmaceutical ingredients in each of the dosage units when compared with

each of the other dosage units.

32. (Previously Amended) The composition of claim 31 wherein the active

pharmaceutical ingredients are free bases or salts selected form the group consisting of

maleate, citrate, chloride, hydrochloride, bromide, hydrobromide, acetate, sulfate,

mesylate, palmitate, and stearate, and combinations thereof.

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33. (Previously Amended) The composition of claim 31 wherein the tannic acid is

natural or synthetic.

34. (Previously Amended) The composition of claim 31 wherein the dispersing agent is

selected from the group consisting of magnesium aluminum silicate, xanthan gum and

cellulose compounds, and combinations thereof.

35. (Previously Amended) The composition of claim 31 wherein the solvents are

selected from the group consisting of purified water, ethanol, diethylether, methylene

chloride, acetone, and isopropyl alcohol, and combinations thereof.

36. (Previously Amended) The composition of claim 31 wherein the diluent is selected

from the group consisting of lactose, microcrystalline cellulose, sucrose and mannitol,

and combinations thereof, and is present in a concentration of about 1.0 to about

75.0%.

37. (Previously Amended) The composition of claim 31 wherein the binder solution

comprises material selected from the group consisting of corn starch, pregelatinized

starch, potato starch, polyvinylpyrrolidone and xanthan gum, and combinations thereof,

and is present in a concentration of about 0.1% to about 20.0%.

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38. (Previously Amended) The composition of claim 37 wherein the binder solution

further comprises a solvent.

39. (Previously Amended) The composition of claim 38 wherein the solvent is selected

from the group consisting of purified water, ethanol, diethylether, methylene chloride,

acetone, and isopropyl alcohol, and combinations thereof.

40. (Previously Amended) The composition of claim 31 wherein the dry binding/matrix

forming agents are selected from the group consisting of methylcellulose, hydroxypropyl

methyl cellulose, ethylcellulose, hydroxypropyl cellulose, xanthan gum and polyvinyl

pyrrolidone, and combinations thereof, and each is present at a concentration of about

0.1% to about 20.0%.

41. (Previously Amended) The composition of claim 31 wherein the coloring agents are

selected from the group consisting of blue, red, yellow, green, orange, and purple, and

combinations thereof, and each is present at a concentration of about 0.01% to about

2.0%.

42. (Previously Amended) The composition of claim 31 wherein the sweetening agents

are selected from the group consisting of sucrose, saccharin sodium, xylitol and

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sucralose, and combinations thereof, and each is present at a concentration of about

0.01% to about 40.0%.

43. (Previously Amended) The composition of claim 31 wherein the flavoring agents are

selected from grape, cherry, orange, lime and strawberry, and combinations thereof,

and is present in a concentration of about 0.01% to about 3.0%.

44. (Previously Amended) The composition of claim 31 wherein the dispersing agent is

magnesium aluminum silicate and is present in about 0.05% to about 15.0% by weight.

45. (Previously Amended) The composition of claim 31 wherein the tannic acid is

present in the range of about 0.05% to about 30.0% by weight.

46. (Previously Amended) The composition of claim 44 wherein the ratio of magnesium

aluminum silicate to tannic acid is present in the weight ratio of 0.1:1 to 100:1.

47. (Previously Amended) The composition of claim 31 wherein the tannic acid and the

active pharmaceutical ingredients are present in the weight ratio 2:1 to 10:1.

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48. (Previously Amended) The composition of claim 31 wherein the tannate salts are pyrilamine tannate present at 30mg and phenylephrine tannate present at 25mg.

- 49. (Previously Canceled)
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- 51. (Previously Canceled)
- 52. (Previously Canceled)

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53. (Presently Amended) A homogeneous composition comprising:

a plurality of active pharmaceutical ingredients comprising tannate salts, the homogeneous composition being in an amount to include a plurality of dosage units, the homogeneous composition being homogeneous in amounts of active pharmaceutical ingredients in each of the dosage units when compared with each of the other dosage units, the homogeneous composition being formed by a method

dissolving the salt or free base of active pharmaceutical ingredients consisting essentially of phenylephrine and pyrilamine in a solvent to form a solution; mixing a dispersing agent and tannic acid in a solvent to form a

dispersion; and

comprising:

transferring at least a portion of the solution to the dispersion, to form tannate salts of the active pharmaceutical ingredients without isolation or purification.